



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0596]

Lung Cancer Patient-Focused Drug Development; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the public docket on lung cancer patient-focused drug development. In the Federal Register of June 5, 2013 (78 FR 33581), FDA announced an opportunity for public comment on this topic and explained that the comment period would close on July 29, 2013. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments to the docket by August 28, 2013.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1199, Silver Spring, MD 20993-0003, 301-796-5003, email: graham.thompson@fd.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 5, 2013 (78 FR 33581), FDA announced an opportunity for public comment on lung cancer patient-focused drug development and explained that the comment period would close on July 29, 2013. The Agency is extending the comment period to allow interested persons additional time to submit comments.

As part of Patient-Focused Drug Development, FDA is gathering patient and patient stakeholder input on symptoms of lung cancer that matter most to patients and on current approaches to treating lung cancer. FDA is interested in patients' perspectives for the two main types of lung cancer (small-cell and non-small cell lung cancer) on the importance of disease symptoms, benefits of treatment approaches, and possible cancer treatment side effects. FDA is interested in receiving patient input that addresses the following questions.

Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients

1. For context, how long ago was your diagnosis of lung cancer? Is your cancer currently in only one area of the lung or has it spread to other parts of the lung or outside of the lungs?

2. Of all the symptoms that you experience because of your lung cancer, which one to three symptoms have the most significant impact on your daily life? (Examples may include pain, cough, shortness of breath, fatigue, voice hoarseness.)

3. Are there specific activities that are important to you but that you cannot do at all, or as fully as you would like, because of lung cancer? (Examples may include sleeping through the night, climbing stairs, household activities.)

Topic 2: Patients' Perspectives on Current Approaches to Treating Lung Cancer

1. Are you currently undergoing any cancer treatments to help reduce or control the spread of your lung cancer? Please describe.

1.1 What do you consider to be the most significant downsides of these treatments?

(Examples of downsides may include side effects, going to the hospital for treatment, frequent blood tests, etc.)

1.2 How do these downsides affect your daily life?

2. What supportive care treatments, if any, are you taking to help improve or manage the symptoms you experience because of your lung cancer? Please include any prescription medicines, over-the-counter products, and other therapies including non-drug therapies (such as breathing techniques).

2.1 What specific symptoms do your treatments address?

2.2 How well do these treatments manage these symptoms?

2.3 Are there symptoms that your current treatment regimen does not address at all, or does not treat as well as you would like?

3. When thinking about your overall goals for treatment, how do you weigh the importance of prolonging your life versus improving the symptoms you experience because of your lung cancer?

4. What factors do you take into account when making decisions about using treatments to help reduce or control the spread of your lung cancer? In particular:

4.1 What information on the potential benefits of these treatments factors most into your decision? (Examples of potential benefits from treatments may include shrinking the tumor, delaying the growth of the tumor, prolonging life, etc.)

4.2 How do you weigh the potential benefits of these treatments versus the common side effects of the treatments? (Common side effects could include nausea, loss of appetite, fatigue, diarrhea, rash.)

4.3 How do you weigh potential benefits of these treatments versus the less common but serious risks associated with the treatments? (Examples of less common but serious risks are developing a hole in the stomach or intestine, liver failure, kidney failure, lung inflammation, blood clot, stroke, heart attack, serious infections, etc.)

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: June 28, 2013.

Leslie Kux,

Assistant Commissioner for Policy.